

c.) REMARKS

Claims 1-15 were originally filed in the application. Claims 16-21 were added in amendments. Claims 2-4 and 9 were previously withdrawn from consideration. Claims 1, 5-8 and 10-21 are rejected in the *final* Office Action. By this paper, claims 1 and 10 are amended. No new claims have been added. Claims 1, 5-8 and 10-21 are pending. Reconsideration of claims 1, 5-8 and 10-21 is respectfully requested.

Claim Rejections – 35 U.S.C. § 103

In the *final* Office Action, claims 1, 5-8, and 10-21 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Feller, Jr., et al. (U.S. Patent No. 4,362,156) in view of Kitrilakis (U.S. Patent No. 3,700,380) or Ersek (U.S. Patent No. 3,638,649) or Helfrich (U.S. Patent No. 5,308,338) or Baudino et al. (U.S. Patent No. 5,848,987). Claims 5-8 depend from claim 1 while claims 11-18 depend from claim 10.

Claims 1 and 10 have been amended herein to recite:

said interface having an exterior surface including texture thereon wherein [cells] microplasts selected from the group consisting of fibroblasts, dermal, subdermal, inflammatory, and collagen grow into engagement with said texture during the bodily process of healing the puncture wound to form a barrier against the migration of foreign matter past said interface and to secure the catheter in place.

Support for this Amendment is found on p. 6, ln.17–p. 7, ln. 1 of Applicant's specification which reads:

An additional important function of texture 22 is that the skin 24 (microplast) surrounding interface 18 will grow in an attempt to close or heal the hole (puncture) through which interface 18 and cannula 20 are inserted such that the cells will grow into engagement with the greater surface area of the interface caused by the texture in an attempt to close the puncture wound caused when the catheter was inserted. This interface between the cells of skin 24 and texture 22 of interface 18 will help deter interface 18 from moving in and out of skin 24 when the patient moves through activity. In this way, the possibility of infection causing germs from entering the puncture wound through skin 24 and the blood stream within vein 26 from the portion of interface 18 extending outside of skin 24 is greatly reduced. Such reduction in the possibility of the introduction of bacteria or fungus into the body is significant in the reduction of serious infection possibilities inherent in the use of the venous catheter. . . .

As used therein, microplasts include cells, and/or tissue which are a part of the healing process of the puncture wound caused when the catheter is inserted. These include fibroblasts, dermal, subdermal, inflammatory, and collagen.

Moreover, the texture of Applicant also acts to secure the catheter in place. This results from *both* microplast (cellular/tissue) ingrowth *and* mechanical (friction) interaction between the interface including the texture and the surrounding tissue.

It is admitted in the Office Action that Feller, Jr. does not disclose an interface having an exterior surface including texture thereon, however, it is asserted that the use of texture on interfaces is conventional in the art as evidenced by the teachings of Kitrilakis, Ersek, Helfrich, or Baudino et al. Applicant respectfully disagrees. None of the cited references teach or suggest a body including

an interface with texture on its exterior surface which secures a catheter in place as a result of microplast ingrowth and mechanical interaction between the interface and the surrounding tissue as recited in Applicant's amended claims 1 and 10. Texture on an interface, as recited in Applicant's claims 1, 10, and 19, is either not disclosed in, or not of the type or for the purpose of the Kitrilakis, Ersek, Helfrich, or Baudino et al. references.

Kitrilakis discloses "a lining or surface containing a plurality of **microcavities or pockets**" which "forms a tenacious base or anchor for pseudointimal growth and tissue ingrowth" (Column 3, lines 18-21). Providing a surface with a microcavity or pocket as disclosed in Kitrilakis is not the same as a texture as recited by Applicant's claims 1 and 10. A "cavity" is an unfilled or hollowed out space and defined in *Webster's New Universal and Unabridged Dictionary*, Random House Value Publishing, Inc. (1996) as "any hollow place." Kitrilakis does not disclose texture.

In contrast, Applicant's claims 1, 10 and 19 recite an interface having an exterior surface including texture thereon. Texture, according to Applicant's present invention, and by definition, is a physical or tactile characteristic structure applied to the exterior surface of the interface which does allow microplast ingrowth to form a physical barrier against the migration of foreign matter past the interface but also provides a mechanical seal (friction) to secure the catheter in place (claims 1 and 10, as amended herein). Applicant's texture may also include a plurality of bumps (claims 5 and 15) which are rounded (claim 6) or pointed (claim 7). Such a texture is not disclosed by Kitrilakis.

Ersek, likewise, does not disclose an interface having an exterior surface including texture thereon. Ersek discloses a synthetic pass through device including an intermediate portion **25** which "is roughened to create a myriad of hairy projections." Intermediate portion **25** is positioned between

a tip **24** and a tubular occlusion member **14**.

In contrast, in the catheter of the present invention, it is a portion of the body (the interface) of the catheter itself which includes texture thereon, not a separate intermediate portion. In addition, Ersek teaches that “a portion of the roughened surface extends into the vessel **13**” (Column 2, lines 32-33). As recited in Applicant’s amended claims 1 and 10, the interface is recited as the “portion of the body which remains in contact with said bodily tissue adjacent said point of insertion.” The cannula extends into and terminates in the vessel.

However, it is perhaps most significant that Ersek does not teach or suggest the use of a texture. Instead, Ersek teaches that the intermediate portion is roughened to create a “myriad of hairy projections.” First, roughening the tube to create hairy projections increases the diameter (gauge) of the tube. Second, these hairy projections could become dislodged and actually cause infection, or worse, be carried into the vessel. Accordingly, Ersek does not disclose texture as recited by Applicant’s claims 1, 5-8, and 10-21.

The Helfrich reference discloses a catheter including annular cuffs at one or more locations along its length. The catheter, as disclosed by Helfrich does not teach or suggest an interface having an exterior surface including texture thereon, as recited in Applicant’s claims 1, 10, and 19.

The Baudino et al. reference teaches the use of “alternating projections and recesses” (Column 3, lines 10-25) in order to “oppose the body’s natural reaction of encapsulating a foreign object.” Baudino et al. is a catheter for dispensing liquids to and from body organs and does not teach or suggest a catheter for insertion into a vessel including texture on its exterior surface which secures a catheter in place as a result of microplasm ingrowth and mechanical interaction between the

interface and the surrounding tissue as recited in Applicant's amended claims 1 and 10.

The Federal Circuit has mandated that a rejection under § 103(a) is only appropriate if there is a "teaching, suggestion, or incentive supporting the combination" relied upon. *In re Geiger*, 815 F.2d 868, 2 USPQ 2d 1276, 1278 (Fed. Cir. 1987). The Federal Circuit went further to state in *Akzo N.V. v. United States International Trade Commission*, 1 USPQ 2d 1241, 1246 (Fed. Cir. 1986), *cert denied*, 482 U.S. 909 (1987), that:

[P]rior art references before the tribunal must be read as a whole and consideration must be given where the references diverge and teach away from the claimed invention... Moreover, appellants cannot pick and choose among individual parts of associated prior art references "as a mosaic to recreate a facsimile of the claimed invention."

Applicant submits that there is no requisite teaching, suggestion or incentive to combine the Feller, Jr., et al. reference with either the Kitrilakis, Ersek, Helfrich, or Baudino et al. references as asserted in the *final* Office Action. In determining obviousness, "the inquiry is not whether each element existed in the prior art, but rather whether the prior art made obvious the invention as a whole for which patentability is claimed." *Hartness International, Inc. v. Simplimatic Engineering Co.*, 2 USPQ2d 1826, 1832 (Fed. Cir. 1987). Applicant submits that it does not. This is just another way to help focus the inquiry on motivation to combine, which must be established by "clear and particular" evidence. *In re Dembiczak*, 50 USPQ2d 1614 (Fed. Cir. 1999).

With specific regard to claims 10-18, which recite an intravenous stent, none of the cited references disclose an intravenous stent. Claims 11-18 depend from claim 10 and are allowable at least for the reasons set forth with regard to claim 10.

Claim 19 recites that the cannula is frustoconical in shape and “wherein said texture provides friction so as to retain said body in the severed vessel.” Claims 20-21 depend from claim 19 and are allowable at least for the reasons set forth with regard to claim 19. By way of summary, the device of claims 19-21 is to provide an intravascular device which is frustoconical so that it can be inserted in a severed vessel for the introduction of medication therein. In this embodiment of the invention, the texture provides friction so as to retain the device in the vessel. None of the above-cited references disclose an intravascular device that is frustoconical in shape and includes texture thereon wherein the texture provides friction to retain the body of the intravascular device in a severed vessel.

In light of the foregoing, the rejection in the *final* Office Action of claims 1, 5-8 and 10-21 under 35 U.S.C. §103(a) is believed overcome. Reconsideration and allowance of claims 1, 5-8, and 10-21 is respectfully requested.

Considering the foregoing, it is sincerely believed that this case is in a condition for allowance, which is respectfully requested.

This paper is intended to constitute a complete response to the *final* Office Action. Please contact the undersigned if it appears that a portion of this response is missing or if there remain any additional matters to resolve. If the Examiner feels that processing of the application can be expedited in any respect by a personal conference, please consider this an invitation to contact the undersigned by phone.

Respectfully submitted,

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